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KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004				CHANNAVAJJALA, LAKSHMI SARADA
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 08/921,533  
Filing Date: September 02, 1997  
Appellant(s): TORMALA ET AL.

**MAILED**  
**MAY 21 2007**  
**GROUP 1600**

Zeba Ali  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 8-21-06 appealing from the Office action  
mailed 4-19-06.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

4,743,257	Tormala et al.	5-1988
4,778,471	Bajpai	10-1988
6,406,498	Tormala et al.	6-2002

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 9-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent 6,406,498 ('498) in view of US 4,743,257 ('257) and US 4,778,471 ('471). Although the conflicting claims are not identical, they are not patentably distinct from each other because '498 teach bioactive, bioabsorbable surgical composite material comprising a bioabsorbable polymer matrix that is oriented and bioactive glass or ceramic particles dispersed in the matrix that is self-reinforced, wherein said particles extend at least into said pores. Thus, the self-reinforced polymeric matrix of '498 reads on the instant composite material having a resorbable matrix, a reinforcing component mixed with said matrix component and a bioglass component in the form of particles. '498 claims particle sizes but fails to claim the specific particle size of 60 to 150 microns. '498 also fail to specify the process steps for preparing the composite material and fiber diameters, a claimed.

'257 teach a self-reinforced surgical osteosynthesis composite material formed by an absorbable polymer or copolymer matrix, which is reinforced with the absorbable reinforcement units and which have the same chemical element percentage composition as the matrix (col. 3-4). With respect to the method of manufacturing, '257 teach mixing together a melt of the absorbable polymer or copolymer and subjecting to heat and pressure (examples and claim 12). '257 teach the same polymeric materials such as those claimed in the instant claim 13 for preparing the matrix and the reinforcing element (examples). Figure 1 of '257 shows the arrangement of the polymeric matrix and reinforcing fibers in the surgical composite material.

'471 teach zinc based ceramic materials that can be used in same applications as hydroxyapatite and other ceramic materials, and used for surgical applications. '471 teach particulate ceramic materials that have particle size of about 1 to 400 microns. '471 teach that for a bone implant device, a particle size of 40 to 200 microns can be used and for drug delivery a particle size of 1 to 38 microns (col. 3, lines 8-16). '471 also teach that the ceramic particles are mixed antibiotics for treating any infection, or hormones, proteins etc (Col. 4 and col. 5). '471 teach delivering the substances from the ceramics by impregnating ceramics with the various polymeric materials (lines bridging cols 4 through col. 5) for successful resorption of ceramic within the body (col. 5).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a bone composite material of '498 employing the process of steps of '257 because '257 teaches that manufacturing the composite materials by the application of heat and pressure results in self-reinforced bioabsorbable materials that have high content of oriented fibers, smooth surface, low porosity and good strength. Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ bioglass or ceramic particles, in an appropriate particle size range in the surgical composite material of '498

depending on the use of ceramic particles as a cement or for drug delivery, because '471 suggests specific particle sizes for either purposes (cement or drug delivery) and suggests that increase in particle size is associated with a decrease in mechanical strength and an increase in porosity. Accordingly optimizing the particle size with an expectation to achieve the desired porosity and mechanical strength of the composite material would have been within the scope of a skilled artisan. Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate a suitable pharmaceutical such as hormone, antibiotic, etc., depending on the treatment because '471 teaches that the success of the implant depends on the ability of ceramic to resorb in the body and also on the type of drug to be delivered. With respect to the claimed volume fraction of the bioglass, absent unexpected results, '471 recognizes various ceramic materials (col. 2) and their particle sizes that are suitable for implant as well as drug delivery purposes and accordingly optimizing the volume of ceramic particles in the implant or composite material of '498 would have been within the scope of a skilled artisan.

#### **(10) Response to Argument**

Appellants argue that the U.S. patent 6,406,498 ('498 patent) recite glass or ceramic particles dispersed in a polymeric matrix but do not recite any size of the particles, let alone a size between 60 microns and 150 microns. It is argued that the U.S. Patent 4,743,257 ('257 patent) does not make up for this deficiency as the '257 patent does not describe any bioglass or bioceramic particles. Appellants arguments are not persuasive because the '257 patent has not been cited for the claimed particle sizes and instead for the teaching of a self-reinforced polymeric matrix, which is claimed in the instant invention.

With respect to the U.S. Patent 4,778,471 ('471 patent), it is argued that there is no motivation to combine the teachings of '471 with the claims of '498 because '498 teaches surgical composite material and '471 teaches a drug delivery system, cement or grout or a preformed implant. It is argued that '471 lacks any suggestion of dispersing the powdered ceramic in any way to form a composite material and instead only teaches the mixing the bioceramic with a setting agent to provide a cement or a grout. Appellants' arguments are not persuasive because admittedly, '471 teach the ceramic particles for a bone implant device (col. 4, L 16-19), which reads on the instant described bone fixation devices (specification page 5, L 15-16). Further, instant claims recite "a composite material for surgical osteosynthesis", where a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure. '471 further teaches particulate ceramic materials for controlled release of drugs or pharmaceuticals, either alone or in combination with a rate controlling polymer such as poly(lactic acid), polyglycolic acid etc (lines bridging col. 4-5). Thus, the particulate resorbable ceramic material of '471 serves the same purpose as that claimed and disclosed in the instant invention. Finally, in order to prepare cement or grout, '471 teaches mixing the ceramic particles with a setting agent (col. 3, 17-30).

Appellants' arguments regarding the unexpected advantage of the claimed particle size has been considered. It is argued that smaller ceramic particles resulted in more giant cells in tissues near and inside the degrading composite as opposed to the fewer giant cells in composites with bigger particle sizes, example 11 of the

specification. '471 teaches ceramic particles in different size ranges for different purposes i.e., 40 to 200 microns for bone implants, 1 to 38 for drug delivery systems and 1 to 400 microns cement or grout (col. 3, L 7-15). Accordingly, choosing the optimum size of the ceramic particles in the composite material of '498, depending the utility of the particles i.e., to delivery pharmaceuticals, as a cement or grout would have been within the scope of a skilled artisan. In this regard, '471 teach specification (page 5, L 15-16) that particle size is directly related to the resorption rate of the ceramic and in turn its drug delivering ability (col. 4, L 34-39 and col. 5, L 3-20).

Appellants argue that the claimed methods of manufacturing are not obvious over the teachings of '498, '257 and '471 because '257 fail to teach the ceramic particles. For the claimed step of mixing the polymer with the ceramic particles, '471 teaches enclosing or impregnating the ceramic particles with a polymer so as to control the release of the pharmaceutical or the drug. Further '257 teaches the method of preparing a self-reinforced polymeric matrix by subjecting the materials to heat and pressure, which allows for the development of adhesion between the nearby reinforcement units and the matrix. '257 further recognize that the self-reinforced surgical material may sometime include fillers or powder-like fillers. Further, the examples (1-13) of '257 describe various methods of solvent mixing, melt mixing or compression molding or mechanical mixing, and thus meet the claimed method.

With respect to the argument regarding the teaching of polymeric reinforcing fibers and their diameters, '257 teaches that the reinforcing elements or materials are in the form of fibers, threads, twits etc (col. 3, L 45-58), and the figure showing reinforcing

fibers of '257 is very much comparable to the instant figure 1. In addition, '257 teach 4.5mm, 4.9 mm etc (see examples of '257), which are much greater than the particle sizes described by '471. Appellants argue that the specific ceramic particles claimed are not taught by '471. However, the ceramic particles of '257 does read on the instant bioceramic materials and further, '257 does recognize hydroxyapatite as the conventional ceramic materials for drug delivery systems and hence optimizing the volume of ceramic particles in the implant or composite material of '498 would have been within the scope of a skilled artisan.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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May 10, 2007



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